

Int. Appln. No.: PCT/US04/11211  
US Appln. No.: To Be Assigned  
US Filing Date: Concurrently  
Case No.: 21170P  
Page No.: 3

Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims:

Claim 1. (original) Form B montelukast sodium characterized as having an x-ray powder diffraction pattern peak position substantially as shown:

2 θ	d spacing (A)	Intensity
5.4	16.4	s
5.7	15.6	vs
9.5	9.3	m
10.4	8.5	m
17.1	5.2	s
18.7	4.73	s
21.6	4.11	s

Claim 2. (original) A pharmaceutical composition comprising a therapeutically effective amount of montelukast sodium Form B of Claim 1 and a pharmaceutically acceptable carrier.

Claim 3. (original) A method for the treatment of asthma or allergic rhinitis which comprises administering to a mammal in need of such treatment a therapeutically effective amount of montelukast sodium Form B of Claim 1.

Claim 4. (original) A method for the treatment of respiratory symptoms associated with viral bronchiolitis which comprises administering to a mammal in need of such treatment a therapeutically effective amount of montelukast sodium Form B of Claim 1.

Claim 5. (original) A method for the treatment of chronic urticaria which comprises administering to a mammal in need of such treatment a therapeutically effective amount of montelukast sodium Form B of Claim 1.

Int. Appln. No.: PCT/US04/11211  
US Appln. No.: To Be Assigned  
US Filing Date: Concurrently  
Case No.: 21170P  
Page No.: 4

Claim 6. (original) A method for the treatment of conjunctivitis which comprises administering to a mammal in need of such treatment a therapeutically effective amount of montelukast sodium Form B of Claim 1.

Claim 7. (original) A method for the treatment of sinusitis which comprises administering to a mammal in need of such treatment a therapeutically effective amount of montelukast sodium Form B of Claim 1.

Claim 8. (original) Montelukast sodium:acetonitrile monosolvate.

Claim 9. (currently amended) Montelukast sodium:acetonitrile monosolvate of Claim 8 characterized by having  $^{13}\text{C}$  solid-state CPMAS NMR chemical shifts in ppm at 72 (sharp triplet), 74 (sharp triplet), 77 (sharp triplet), 179 (sharp doublet), and 182 (sharp doublet).

Claim 10. (original) Montelukast sodium:acetonitrile monosolvate of Claim 8 further characterized by having X-ray powder diffraction peaks substantially as shown:

2 $\theta$	d spacing (Å)	Intensity
4.30	20.5	vs
5.9	14.9	s
6.2	14.3	s
6.8	13.0	w
7.3	12.0	w
10.5	8.4	m
11.0	8.0	w
12.7	7.0	m
16.2	5.5	s
18.1	4.90	w
18.7	4.74	w
21.6	4.12	w
23.4	3.80	w
23.9	3.72	w

Int. Appln. No.: PCT/US04/11211  
US Appln. No.: To Be Assigned  
US Filing Date: Concurrently  
Case No.: 21170P  
Page No.: 5

Claim 11. (original) Montelukast sodium:acetonitrile hemisolvate.

Claim 12. (original) Montelukast sodium:acetonitrile hemisolvate of Claim 10 characterized by having  $^{13}\text{C}$  solid-state CPMAS NMR chemical shifts in ppm at 27 (well resolved) and 55 (well resolved), referenced by setting the carbonyl resonance of glycine to 176.08.

Claim 13. (original) Montelukast sodium:acetonitrile hemisolvate of Claim 10 characterized by having X-ray powder diffraction peaks substantially as shown:

2 $\theta$	d spacing (Å)	Intensity
4.57	19.3	s
5.3	16.7	s
5.6	15.7	vs
6.5	13.6	m
9.4	9.4	m
10.3	8.6	w
11.6	7.6	m
14.1	6.3	w
14.5	6.1	m
15.1	5.8	w
16.2	5.5	m
17.0	5.2	m
18.5	4.79	s
20.8	4.26	m
21.3	4.17	s

Claim 14. (original) A method for the preparation of montelukast sodium Form A substantially free of amorphous montelukast sodium comprising: 1) collecting montelukast sodium:acetonitrile monosolvate; and 2) removing acetonitrile from the collected monosolvate.

Claim 15. (original) A method for the preparation of montelukast sodium Form A substantially free of amorphous montelukast sodium comprising: 1) contacting

Int. Appln. No.: PCT/US04/11211  
US Appln. No.: To Be Assigned  
US Filing Date: Concurrently  
Case No.: 21170P  
Page No.: 6

amorphous montelukast sodium or a mixture of amorphous montelukast sodium and montelukast sodium Form A with acetonitrile to form montelukast sodium:acetonitrile monosolvate; 2) collecting said monosolvate; and 3) removing acetonitrile from the collected monosolvate.

Claim 16. (original) The method of Claim 14 wherein a mixture of amorphous montelukast sodium and montelukast sodium Form A is used in step 1).